A Faustian Bargain On Labeling Genetically Engineered Food

By Henry I. Miller and Drew L. Kershen

Pseudo-controversy continues to rage over whether foods from plants and animals genetically engineered with the newest molecular techniques should be identified as such. The battle has been fought in the media, state legislatures, referendum issues, and in federal courts. Funded and supported by the organic food industry, the pro-labeling groups, radical environmental organizations, food activists, TV celebrities and other assorted antagonists have stopped at nothing. They have lied, defamed, misrepresented and threatened.

In recent years, the majority of proposals to require labeling have gone down in flames. However, in spite of the fact that mandatory labeling fails every test – scientific, economic, common-sense – and that even activists’ “successes” are likely to be reversed as unconstitutional when they are challenged in the federal courts, the true believers soldier on.

Understandably, the food, farm and agribusiness industries are tired of fighting these endless brush fires. Hoping to extinguish them once and for all, they have come up with a sweeping solution. Unfortunately, it is facile and even worrisome.

Food companies and farm organizations have created the Coalition for Safe Affordable Food (CFSAF), which is lobbying for federal legislation with four goals:

- **Eliminate confusion and uncertainty** caused by the prospect of a 50-state patchwork of safety and labeling laws for genetically engineered food, by affirming that Food and Drug Administration (FDA) is the definitive national authority.

Congress should explicitly preempt state and local safety and labeling laws, which are inherently misleading because they imply that genetically engineered ingredients are a “category” whose members are less safe or nutritious than others. But genetically engineered organisms and the foods derived from them do not in any way constitute real “categories,” which makes any choice of what to include in them wholly arbitrary and misleading. Nor have they been shown to be less safe or in any way less “natural” than thousands of other common foods. In fact, as federal regulators have said, labeling to identify food derived from plants modified with the newest techniques of genetic engineering (as some have proposed) would erroneously imply a meaningful difference where none exists.

In an ideal world, Congress could pass legislation to affirm that the FDA is the sole authority to require mandatory labeling and that, as the FDA announced in a 1992 policy statement, labeling is appropriate to convey “material” information that bears on safety or usage. As FDA said at the time, such risk-related factors in the context of novel foods could include the presence of a completely new substance in the food supply, an increase in the level of a natural food toxin, or the presence of a potent allergen where a consumer would not expect to encounter it.
**Additional regulation** – require the FDA to conduct a safety review of all new genetically engineered traits before they are introduced into commerce.

Although laboratory research on plants has been robust since the invention of molecular genetic engineering techniques in the early 1970’s, the commercialization of products has been slowed by unscientific, excessive government regulation that discriminates against modern, molecular genetic engineering techniques. For a quarter century, genetically engineered crops have been the most scrutinized in human history, without any scientific justification for such a burden. They are far more precisely and predictably crafted than their predecessors, and none has caused documented harm to humans or disruption to an ecosystem.

Hundreds of risk-assessment experiments as well as innumerable observations of “real-world use” have confirmed the safety of the technology. In spite of this vast amount of evidence, there has been no reduction or rationalization of the regulatory burden placed on plants made by the newer techniques of genetic engineering. Indeed, in many cases regulatory stringency and burdens are actually increasing, sometimes in the naïve hope that this will reassure skeptics.

This proposal by CFSAF would represent yet another escalation of regulation, without any justification for it – except perhaps as a bargaining chip for the creation of explicit prohibitions against state and local regulation. That is not a sufficient justification.

At present, the FDA operates a voluntary consultation program for genetically engineered foods whereby the developer provides the FDA various information about the product. Published reports indicate that developers have without exception used this voluntary consultation and that the voluntary consultation is more than adequate to protect the American consumer. There is a broad consensus that there is no scientific reason to consider food made with modern molecular techniques fundamentally different from other food: Corn is still corn regardless of the breeding method used to produce the seed. Therefore, even the “voluntary” consultation – which no food producer dares to flout – is gratuitous and excessive. (Virtually identical foods made with older, less precise and less predictable techniques are not routinely subject to review, voluntary or otherwise.)

Another concern is that a required FDA review and approval of new genetically engineered foods would constitute a “major federal action” that would trigger FDA procedural obligations under NEPA, the federal National Environmental Policy Act. In the past, activists acting in bad faith have delayed approvals by bringing numerous nuisance lawsuits that claimed purely procedural deficiencies under the Act.

Other concerns include gratuitous delays in the review of applications. For example, under its authority to regulate “veterinary drugs,” FDA floundered for more than 15 years reviewing the AquAdvantage genetically-engineered, fast-growing salmon. Then, as the application neared the finish line, for political reasons the approval was hijacked by the Obama White House, where seemingly it has vanished into an Alice-in-Wonderland rabbit hole. This regulatory debacle has forced some U.S. animal genetic engineering researchers to take their promising research to other countries such as Brazil and China, because those nations appear to provide a friendlier regulatory regime. An entire, once-promising sector of U.S. biotechnology has evaporated.
Let’s be clear: CFSAF’s intended changes would do absolutely nothing to enhance the safety of the food supply. In fact, by creating even more burdensome regulation and uncertainty about the path to the marketing of important new products, it would do exactly the opposite. Regulatory changes are in order, but they should be in the direction of making regulation more scientific and risk-based — not mandatory regulatory oversight focused on a bogus pseudo-category.

And that brings up perhaps the greatest concern of all about the CFSAF effort – that Congress is among the loosest of loose cannons, and once it is engaged in crafting legislation, given the reality of low scientific literacy and political horse-trading, there’s no telling where we’ll end up.

Inform Consumers. The FDA would establish federal standards for companies that want to label their product voluntarily to indicate the absence or presence of food ingredients produced with molecular genetic engineering techniques.

Voluntary labeling allows consumers to make choices about what to purchase. Companies will make decisions about when to label, in order to inform consumers generally or to appeal to consumer preferences. But federal law requires that food labels be truthful and not misleading, and labels that imply any sort of warning about genetic engineering are, by definition, misleading.

FDA could provide guidance about the use of specific terms such as “GMO free” or “Non-GM verified,” along with specifying the paperwork that’s required to document such a claim, just as the agency did years ago for dairy products from cows not treated with the protein bovine somatotropin. (However, FDA has not enforced those rules consistently, and many dairy products continue to bear misleading labels.)

This undertaking would be far more difficult than it might seem, however, and in the end would arguably be a fool’s errand, not unlike trying to decide how many Lexus parts could be used in a Toyota without needing to provide a “warning” label or rename the vehicle. The difficulty arises from the fact that genetic engineering is only a tool, and although the resulting products – plants, animals or microorganisms — may possess novel traits, alternatively they may be completely indistinguishable from the same product produced via different, “conventional” technologies.

Another argument for involving FDA in defining these terms is that the agency’s decisions will preempt state and local food laws, again avoiding a patchwork of arbitrary and possibly inconsistent requirements. Moreover, if federal regulators exercise their authority to define terms, companies using them appropriately on labels would gain a safe harbor from litigation under state and local food laws. Consumers would benefit from uniform terminology, and companies would gain certainty about which terms are allowable.

Provide Consistency. The FDA would define the term “natural” for use on food and beverage products so that food and beverage companies and consumers have a consistent legal framework that will guide food labels and inform consumer choice.

This is another red herring. During the past decade, numerous class-action lawsuits have been brought against food companies seeking damages for false advertising when the company placed the words “all natural” or “100% natural” on the label of a food product. In spite of many
requests, some from federal trial judges, FDA has consistently declined to define the term “natural” — most recently in January — pleading that it has higher priorities for its time and resources than getting into a years-long philosophical and ideological quagmire. At best, this exercise would have nothing at all to do with the healthfulness or quality of the food; in effect, it would be the regulatory equivalent of trying to determine how many angels can dance on the head of a pin.

In summary, legislation could be useful, but it should contain only those provisions that are necessary and sufficient — namely, confirmation that FDA policies on genetically engineered foods preempt those of states and localities, and an endorsement of the existing USDA-National Organic Program policy that inadvertently introduced amounts of genetically engineered materials in organic products do not deprive those products of the “organic” label.

CFSAF’s goals are understandable, but in pursuing them the coalition needs to balance science, common sense, and the reality of congressional illogic and unpredictability. CFSAF – and Congress — must ensure that by singling out one technology for relief from harassment, their actions do not perpetuate the myth that genetic engineering is some sort of homogenous “category” amenable to generalizations. It is not, and legislation that treats it as such, even with the best intentions, would be misguided and subject to a more magisterial influence: the Law of Unintended Consequences.

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